Claims

1. A method for determining a subject having a risk of having developed or developing prostate cancer, which comprises the following steps:

   a) a step of analyzing the presence/absence or level of mutation in the PCA-1 gene derived from the subject; and

   b) a step of evaluating the presence/absence or level of the subject's risk of having developed or developing prostate cancer, based on the presence/absence or level of mutation in the PCA-1 gene.

2. The method of claim 1, wherein the mutation is selected from the group consisting of a missense mutation, a nonsense mutation, a silent mutation and a frame shift mutation due to deletion.

3. The method of claim 2, wherein the missense mutation causes an amino acid mutation selected from the group consisting of mutation of the 7th arginine to leucine, mutation of the 8th alanine to valine, mutation of the 30th alanine to threonine, mutation of the 41st threonine to isoleucine, mutation of the 73rd aspartic acid to asparagine, mutation of the 137th glycine to arginine, mutation of the 144th serine to proline, mutation of the 228th aspartic acid to glutamic acid, mutation of the 233rd glutamic acid to aspartic acid, and mutation of the 261st lysine to asparagines, in PCA-1 polypeptide.

4. The method of claim 3, wherein the missense mutation causes an amino acid mutation selected from the group consisting of mutation of the 228th aspartic acid to glutamic acid, mutation of the 233rd glutamic acid to aspartic acid, and mutation of the 261st lysine to asparagines, in PCA-1 polypeptide.

26

5. The method of claim 4, wherein the missense mutation causes a mutation of the 228th aspartic acid to glutamic acid in PCA-1 polypeptide.

6. The method of claim 3, wherein the missense mutation is selected from the group consisting of mutation of the 426th guanine to thymine, mutation of the 429th cytosine to thymine, mutation of the 494th guanine to adenine, mutation of the 528th cytosine to thymine, mutation of the 623rd guanine to adenine, mutation of the 815th guanine to adenine, mutation of the 836th thymine to cytosine, mutation of the 1090th cytosine to guanine, mutation of the 1105th adenine to thymine, and mutation of the 1189th adenine to thymine, in PCA-1 gene.

7. The method of claim 6, wherein the missense mutation is selected from the group consisting of mutation of the 1090th cytosine to guanine, mutation of the 1105th adenine to thymine, and mutation of the 1189th adenine to thymine, in PCA-1 gene.

8. The method of claim 7, wherein the missense mutation is mutation of the 1090th cytosine to guanine in PCA-1 gene.

9. The method of claim 2, wherein the nonsense mutation causes mutation of the 261st lysine to a stop codon in PCA-1 polypeptide.

10. The method of claim 9, wherein the nonsense mutation is mutation of the 1187th adenine to thymine in PCA-1 gene.

11. The method of claim 2, wherein the silent mutation is selected from the group consisting of mutation of the 568th thymine to cytosine and mutation of the 1132nd guanine to thymine, in PCA-1 gene.

27

12. The method of claim 11, wherein the silent mutation is mutation of the 1132nd guanine to thymine in PCA-1 gene.

5 13. The method of claim 2, wherein the deletion is a deletion of the residue from the 777th adenine to the 865th cytosine in PCA-1 gene.

14. The method of claim 1, which comprises the following
10 steps:

a) a step of isolating or purifying a polynucleotide from the subject;

b) a step of amplifying a PCA-1 gene from the polynucleotide;

c) a step of determining the base sequence of the amplified
15 PCA-1 gene;

d) a step of analyzing the presence/absence or level of mutation in the PCA-1 gene derived from the subject;

e) a step of evaluating the presence/absence or level of the subject's risk of having developed or developing prostate
20 cancer, based on the presence/absence or level of mutation in the PCA-1 gene.

15. A polynucleotide comprising a base sequence having not less than one substitution or deletion selected from the group
25 consisting of substitution to the 426th guanine to thymine, substitution of the 429th cytosine by thymine, substitution of the 494th guanine by adenine, substitution of the 528th cytosine by thymine, substitution of the 623rd guanine by adenine, substitution of the 815th guanine by adenine,
30 substitution of the 836th thymine by cytosine, substitution of the 1090th cytosine by guanine, substitution of the 1105th adenine by thymine, substitution of the 1189th adenine by thymine, substitution of the 1187th adenine by thymine, substitution of the 568th thymine by cytosine, substitution of

28

the 1132nd guanine by thymine, and deletion of a sequence from the 777th adenine to the 865th cytosine, as compared to SEQ ID; No 1.

16. A polypeptide comprising an amino acid sequence encoded by a base sequence having not less than one substitution or deletion selected from the group consisting of substitution to the 426th guanine to thymine, substitution of the 429th cytosine by thymine, substitution of the 494th guanine by adenine, substitution of the 528th cytosine by thymine, substitution of the 623rd guanine by adenine, substitution of the 815th guanine by adenine, substitution of the 836th thymine by cytosine, substitution of the 1090th cytosine by guanine, substitution of the 1105th adenine by thymine, substitution of the 1189th adenine by thymine, substitution of the 1187th adenine by thymine, and deletion of a sequence from the 777th adenine to the 865th cytosine, as compared to SEQ ID; No 1.

17. An antibody immunospecifically recognizing the polypeptide of claim 16.

18. A kit for determining a subject having a risk of having developed or developing prostate cancer, which comprises a reagent for PCA-1 gene mutation analysis.

19. The kit of claim 18, further comprising a written matter associated therewith, the written matter stating that the reagent for PCA-1 gene mutation analysis can or should be used for determining a subject having a risk of having developed or developing prostate cancer.